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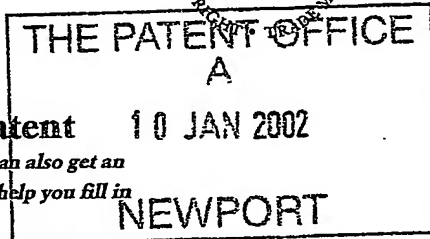
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Stephen Hordley

Dated

12 February 2003

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10JAN02 0886691-6 001559
P017700 0.00-0200444.8

Request for grant of a patent

10 JAN 2002

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1. Your reference

SL/SMR/OML.58

2. Patent application number

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0200444.8

10 JAN 2002

3. Full name, address and postcode of the or of each applicant (underline all surnames)

Owen Mumford Limited
Brook Hill
Woodstock
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OX20 1TU.

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

United Kingdom

4413738002

4. Title of the invention

Improvements relating to Medical Injection Devices

5. Name of your agent (if you have one)

Wynne-Jones, Lainé & James

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

22 Rodney Road
Cheltenham
Gloucestershire
GL50 1JJ

Patents ADP number (if you know it)

1792001

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Date of filing
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Number of earlier application

Date of filing
(day / month / year)

n/a

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

- a) any applicant named in part 3 is not an inventor, or
 - b) there is an inventor who is not named as an applicant, or
 - c) any named applicant is a corporate body.
- See note (d))

Patents Form 1/77

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Continuation sheets of this form

Description 12 /

Claim(s) -

Abstract -

Drawing(s) 6 + 6

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Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

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Any other documents (please specify)

11. I/We request the grant of a patent on the basis of this application.

Signature

S. Lainé Date

9th January 2002

12. Name and daytime telephone number of person to contact in the United Kingdom

01242 515807

Mr. S. Lainé

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Improvements relating to Medical Injection Devices

This invention relates to medical injection devices.

It is of course of great importance that when an injection is carried out the correct dosage is delivered.

5 Many injection devices can administer fixed doses or have some arrangement for setting them up so that, when actuated, the desired correct dose is automatically ejected from the needle. A common design is to have a knob at the rear end of the device which is turned against a scale to
10 indicate the dose, this at the same time adjusting the travel of the syringe plunger when the device is actuated.

However, there is also the matter of delivering the correct number of injections per day, per week or per month. It is quite easy, particularly for people with non-
15 routine lives, to miss an injection, or even to administer an extra one having forgotten that an appropriate injection has already been given. It is not known that any current injection devices provide guidance to help the user maintain regular use.

20 According to one aspect of the present invention there is provided a dose counter for an injection device with a dose setting element, the counter having a member with a lost motion connection to the dose setting element, whereby movement of said element by and beyond a predetermined

amount causes movement of said member to a set extent, each such movement of said member resulting in the indication of usage of the injection device.

According to another aspect of the present invention

5 there is provided a dose application counter for an

injection device with a dose setting knob rotatable with respect to the body of the device, the counter comprising a rotatable ring with an annular array of projections coaxial with the knob, the minimum dose requiring the knob to
10 be turned from a zero position through an angle at least as great as the angular spacing of adjacent projections, an element rotatable with the knob and spring urged to engage a projection when the knob is at zero, and a cam fixed to the body of the device and arranged to disengage the
15 element from the ring when the projection has been pushed round by the element through a predetermined angle and to maintain that disengagement on further rotation, the ring and body having external markings to indicate the circumferential advances of the ring, wherein the
20 application of a dose and the consequent reversion of the knob to its zero position brings said element back to engage another projection while the ring remains static.

Conveniently, the ring will be between the knob and the body of the device.

In the preferred form there will be ratchet teeth internal of the ring which form the projections, and the element that engages them may then be a peg that extends in the axial direction beyond the ring for co-operation also with the cam. This may be another co-axial ring, but with its circular aperture expanded outwards over a sector corresponding to the pitch between adjacent teeth. The radius of most of this aperture will be less than that of the circle tangential to the tips of the teeth and will keep the peg engaged with it clear of them, but the expanded portion will allow the peg to move outwards so that it can engage a tooth registering with that portion. The cam ring will be positioned so that initially, at the zero position of the knob, the peg lies at one circumferential end of the enlargement and, when the knob is rotated, it will move towards the other end, there to be forced radially inwards to clear the teeth on further rotation of the knob.

The peg may be at the free end of a generally spiral finger whose other end is rotationally fast with the knob, the finger being of a plastics material and being so shaped and dimensioned that it acts as a spring.

According to another aspect of the present invention there is provided a dose application counter for an

injection device with a non-rotatable plunger retractable from the rear end of a syringe housing to set a dose and movable forwards into the housing on ejection of the dose, the counter comprising a unidirectionally rotatable sleeve with multi-start internal screw threading carried by the

5 housing, a projection resiliently carried by the plunger, which passes through the sleeve and which through its projection and the screw threading generates rotation of the sleeve as it is retracted, the minimum dose requiring
10 the projection to traverse at least the full axial length of the sleeve and the screw threading being shaped so that the resilient projection jumps threads on forward movement of the plunger, when the sleeve is held against counter-rotation, and external markings on the sleeve and housing
15 to indicate the circumferential advances of the sleeve.

The unidirectional rotation can be achieved by having a ratchet engagement between the sleeve and the housing.

The screw threading will conveniently be coarse pitch square section grooves and the length of the sleeve will be
20 such that the rear end of each part-helical groove will register in the axial direction with the forward end of the adjacent groove. However, to ease the jumping of the threads, the sides of the grooves that face circumferentially and slightly rearwardly can be chamfered

at their rear ends so that, as the plunger moves forward, the projection hits a sloping surface that wedges the projection inwards onto the land area between adjacent grooves. It then snaps out into the adjacent groove and emerges from the forward end of that groove, leaving the sleeve rotated from its pre-dose setting position by an amount equal to the circumferential spacing of the grooves.

When the next dose is set, the projection re-enters the groove previously vacated and indexes the sleeve around again by the same amount.

For a better understanding of the invention, one embodiment will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a perspective exploded view of the rear end of an injection device with a dose counter,

Figure 2 is a perspective view of the device as assembled,

Figure 3 is a plan view of a cam ring forming part of the dose counter,

Figure 4 shows a sequence of plan views of the dose counter as the injection device is operated,

Figure 5 shows side views of another injection device before and after dose setting,

Figure 6 is a perspective view, in ghost, of the device of Figure 5,

Figure 7 is an enlarged detail, in partial axial section, of the device showing a dose counter,

5 Figure 8 is a perspective view from the rear of a sleeve forming a major part of the dose counter,

Figure 9 is a perspective view from the front of the sleeve, with part of a plunger by which a dose is set, and

10 Figure 10 is an exploded perspective view of the sleeve and the rear end of the housing of the injection device.

15 The injection device of Figures 1 to 4 is mostly of conventional form with a cylindrical housing 1 to receive the cartridge of a syringe whose needle 2 projects from the forward end. An actuating mechanism for the syringe plunger is housed in a barrel 3 which attaches to the rear end of the housing 1. A trigger 4 releases this mechanism to eject the dose, which is set by a rotatable knob 5 at the rear end of the barrel 3. A circumferential scale on the knob 5 has numbers to register with a marker 6 on the barrel 3, and the knob is clicked round from the zero position until the desired number is opposite the marker 6. 20 When the trigger 4 is pressed the corresponding dose is ejected and the knob 5 returns to the zero position.

However, between the knob 5 and the barrel 3 there is a co-axial ring 7 whose outer cylindrical surface, flush with those of the barrel and knob, is marked with letters indicating the days of the week. These are regularly spaced around the ring, and internally that ring has a corresponding number of ratchet teeth 8. The rear end of the barrel 3 is plugged by another co-axial ring 9, this having a mostly circular aperture with a part-cylindrical surface 10, but with an enlargement 11. One circumferential end 12 of this enlargement is radial to the ring 9 and the other end is tangential to the surface 10 and forms a cam 13. The end 12 faces in the opposite circumferential direction to the radial working faces of the ratchet teeth 8, the radius of the surface 10 is less than that of the circle tangential to the tips of those teeth and the radius of the enlargement 11 is equal to that of the circle through the roots of the teeth.

The knob 5 has a co-axial shaft 14 extending through these rings 7 and 9 into the barrel 3 to co-operate with mechanism for setting the dose. The shaft 14 is axially grooved and closely fitted by a hub 15 of an indexer 16, the hub having internal splines 17 which engage the grooves in the shaft so that the indexer rotates with the knob 5. The exterior of the hub has a short radial projection 18 at

the outer end of which there is integrally formed a semi-circular finger 19 co-axial with the hub 15 in its relaxed state. Being of moulded plastics, it will have a certain resilience and be able to act as a spring. Although not a true spiral, it approximates to that shape. At the end of the finger 19 there is a peg 20 extending parallel to the axis and of greater length than the thickness of the ring 7.

When assembled, as in Figure 4a, the indexer 16 lies immediately to the rear of the ring 7 with the finger 19 bearing on the sides of several teeth 8, and with the peg 20 engaged with the working face of one such tooth and extending forward into the enlargement 11, where its tip is adjacent the end 12. One of the letters on the outer surface of the ring 7 is in registry with the marker 6.

When the injection device is to be used, the knob 5 is rotated from its zero position, and this rotates the indexer 16, which through its peg 20 turns the ring 7 by pushing on one of the teeth 8. This movement is shown in Figures 4b and 4c. But when the latter position is reached, the free end portion of the peg 20 meets the cam 13, and on continued rotation of the knob 5, the peg 20 is forced radially inwards to clear the tooth 8 that it has just been pushing against. This is shown in Figure 4d.

The ring 7, having been shifted through one-seventh of a complete revolution is then left stationary while the knob 5 is turned further to whatever dose is required.

When the trigger 4 is pressed, the knob 5 winds back again to its zero position, taking with it the indexer 16. The peg 20 is still held clear of the ring 7 until it hits the sloping side of the tooth following the one which it had previously pushed. As the knob finally reverts to zero, the peg 20 slides along that slope and then snaps outwardly after passing the tip.

Although when the finger 19 is bent into tighter curvature during dose setting it reduces its engagement with the sides of certain teeth, it will be seen from Figure 4d that there is still enough to maintain its axial location.

There will now show on the exterior of the injector a new letter opposite the marker 6 indicating to the user that the day's dose has been administered.

It will be understood that rings 7 and 9 of different geometry and different markings could be fitted to cater for a pattern of injections different from one a day for a week.

There are other types of injection devices where, instead of setting the dose by rotating a knob, a plunger

is simply pulled back to a selected degree from the rear end of the housing for the syringe. A counter for this type of device is shown in Figures 5 to 10.

5 The device has a barrel 21 with a forward end cap 22 that initially protects the needle of a syringe 23 within the barrel. At the rear end of the barrel there is a plunger 24 which can be pulled back from the Figure 5a to the Figure 5b position, thereby setting the dose to be administered. During this retraction, as will be described
10 in more detail below, a sleeve 25 co-axially carried at the rear end of the barrel 21, and through which the plunger 24 passes, is indexed round in steps indicated by an arrow 26 on the barrel co-operating with letters on the outside of the sleeve 25 corresponding to days of the week. In this
15 example, the sleeve is moved from Sunday to Monday by the dose setting. When the plunger moves forwards and the dose is ejected the sleeve remains static.

Referring to Figures 7 to 10, the sleeve 25 has an outward flange 27 at its forward end by which it is made
20 captive to the barrel 21 through a cap 28. The forward side of this flange 27 has an annular array of teeth 29 which co-operate with a complementary set of teeth 30 on an inwardly projecting rib 31 of the barrel 21. This limits the forward movement of the sleeve 25, but there is

enough axial play allowed by the cap 28 for the teeth 29 to ride over the teeth 30. Although illustrated as symmetrical, the teeth will preferably be shaped as for ratchets so that, when engaged, rotation in one direction only is possible.

Internally the sleeve 25 is formed with part-helical grooves 32, square cut and open at both ends. They are evenly spaced, and there are seven of them. The rear end of each groove 32 is aligned in the axial direction with the forward end of the adjacent groove. Towards the rear end of each groove the side that faces circumferentially and slightly rearwardly is chamfered so that there is a sloping ramp 33 leading inwards and forwards onto the part-cylindrical land area 34 between adjacent grooves 32.

The plunger 24 is tubular, and at an intermediate point it has a U-shaped cut out 35 which forms a tongue 36 pointing forwardly, and at the free end of this tongue there is an outward projection or stud 37. The thickness and nature of the plastics material of which the plunger is made renders the tongue 36 stiffly resilient.

In the position of Figure 5a, the stud 37 is forward of the sleeve 25, but aligned with the forward end of one of the grooves 32. As the plunger 24 is retracted, the stud enters that groove and, acting on the side facing

circumferentially and forwardly urges the sleeve 25 round by screw-action. The teeth 29, 30 allow this. When the stud 37 emerges from the rear end of the groove, the sleeve has been indexed round one seventh of a complete

5 revolution. This movement corresponds to setting the minimum dose; larger doses may be set, with the stud 37 drawing well clear to the rear of the sleeve 25, but whatever dose is set the sleeve only rotates by that predetermined amount.

10 When the dose is administered, the plunger is moved forwards and the stud 37 re-enters the groove 32 by which it indexed the sleeve. But this time it meets the chamfer 33, and the tongue 36 is flexed inwards by a wedging action between the stud 37 and that chamfer. The stud 37 then
15 reaches the land area 34, and subsequently snaps out into the next groove, at its forward end. This thread jumping action pushes the ratchet teeth 29, 30 together, although this may be achieved with more certainty by spring action, and the sleeve 25 is prevented from rotating back. When
20 the dose has been administered, the plunger 24 is in the Figure 5a position again, but with a new letter showing against the arrow, indicating that the dose for that day has been taken.

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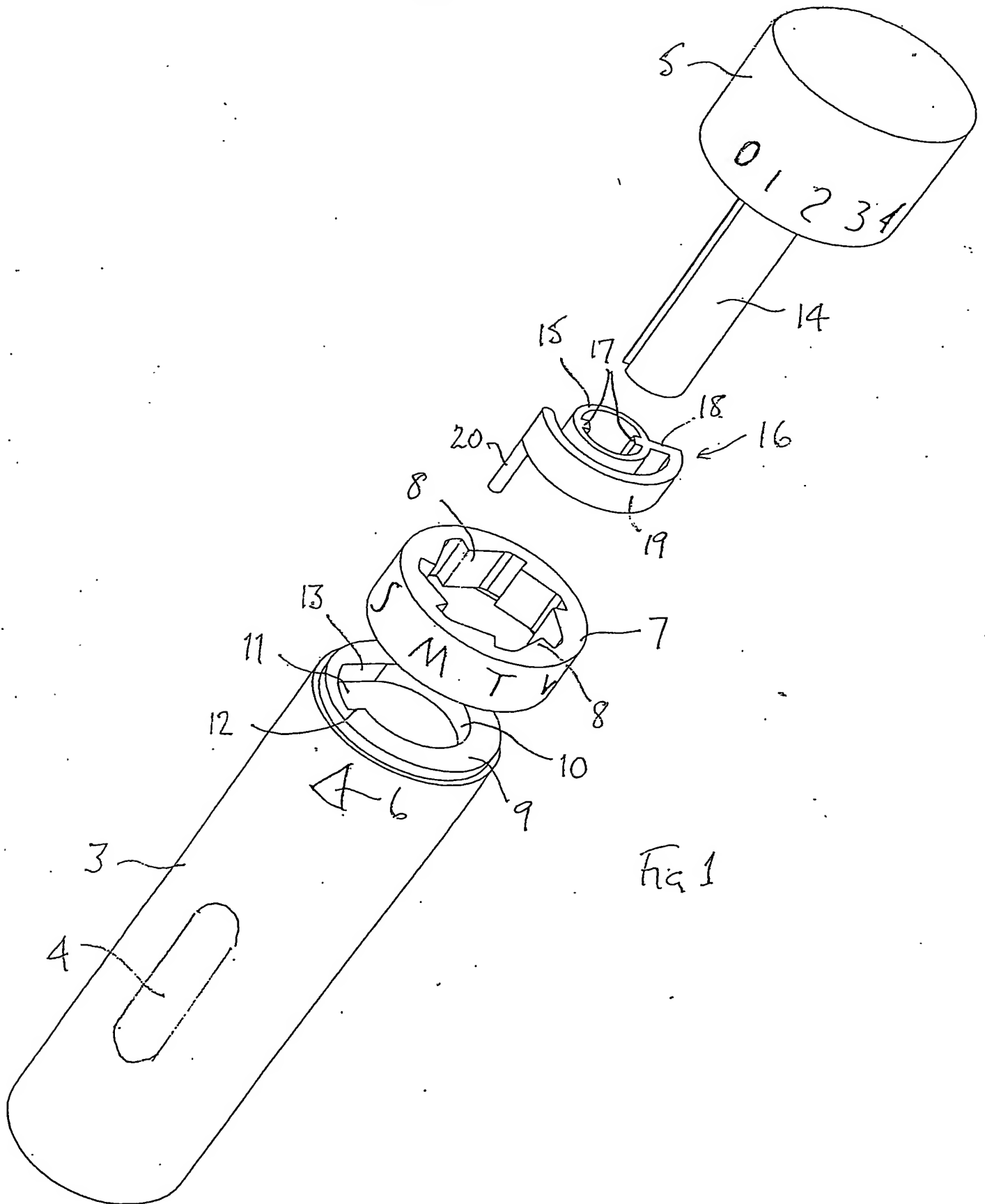


Fig 1

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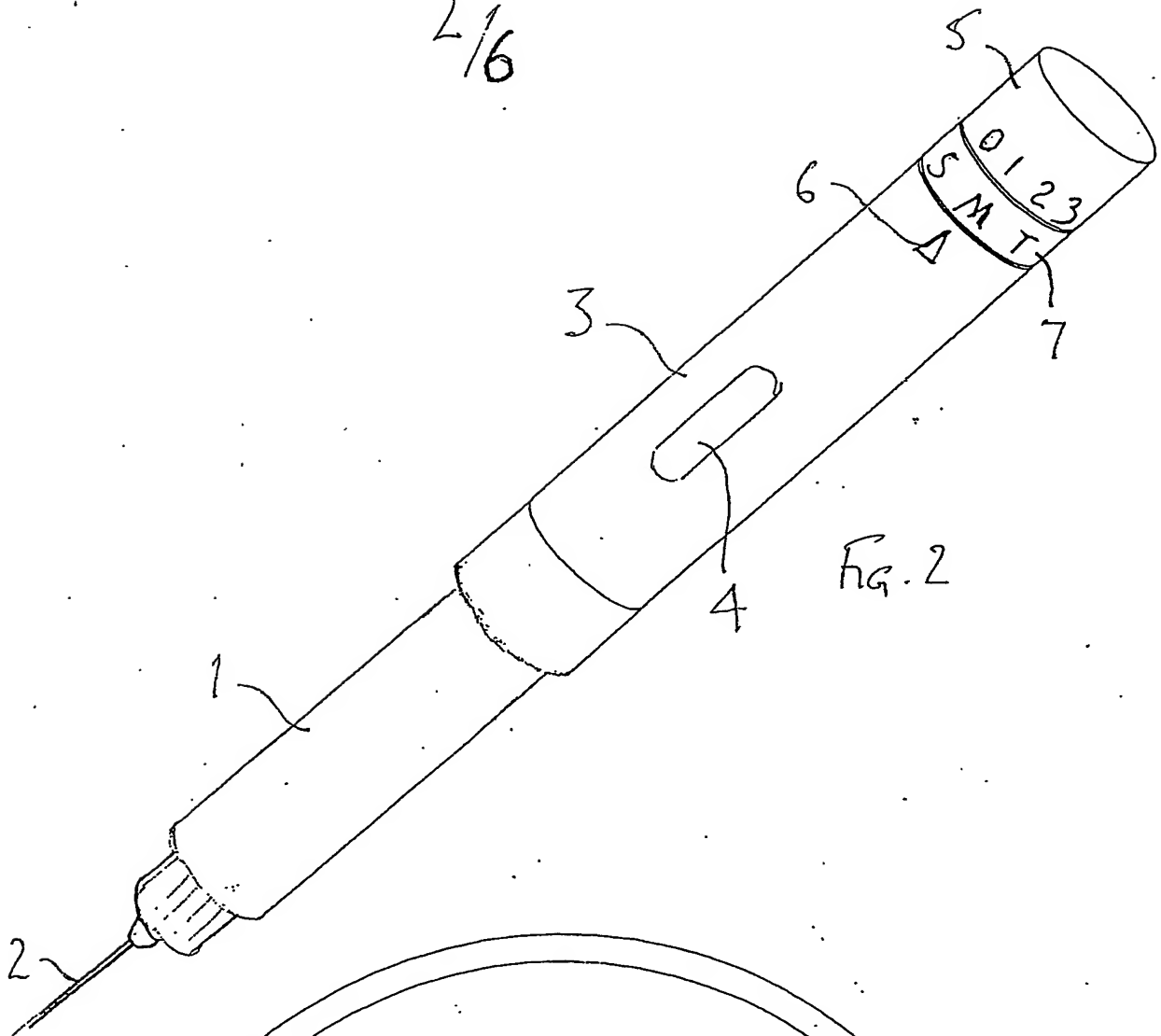


FIG. 2

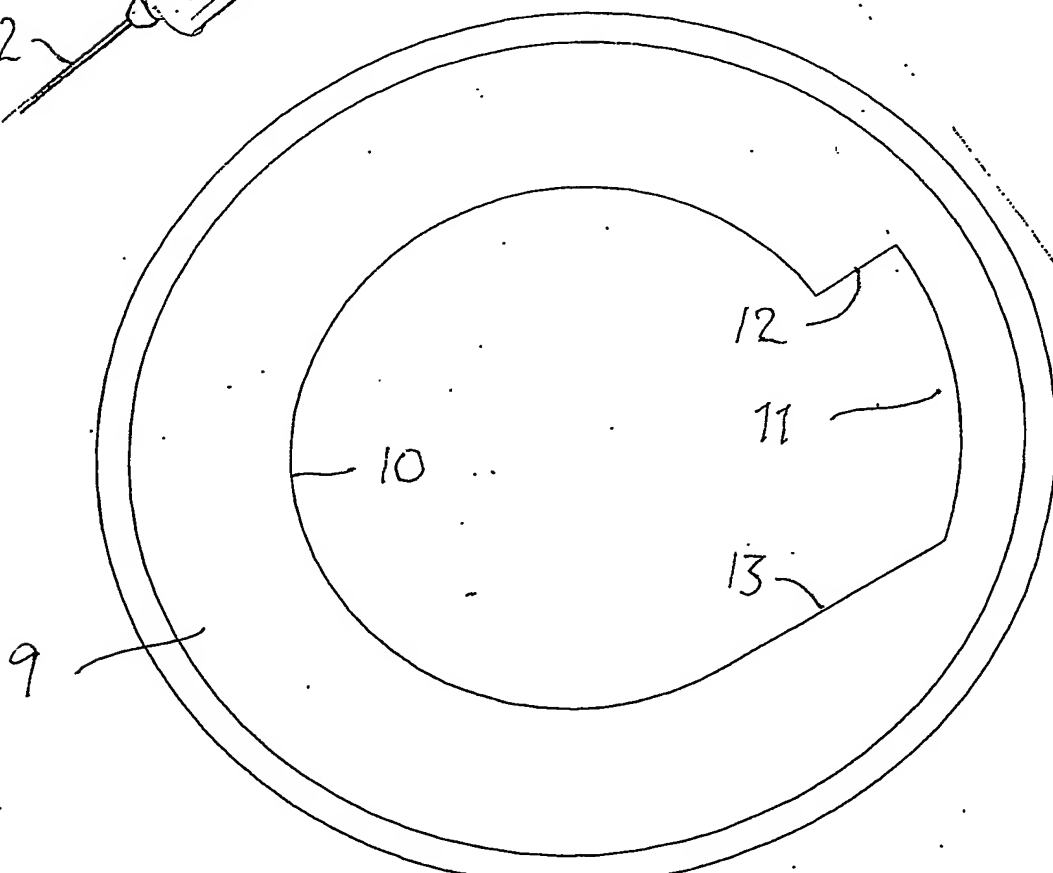


FIG. 3

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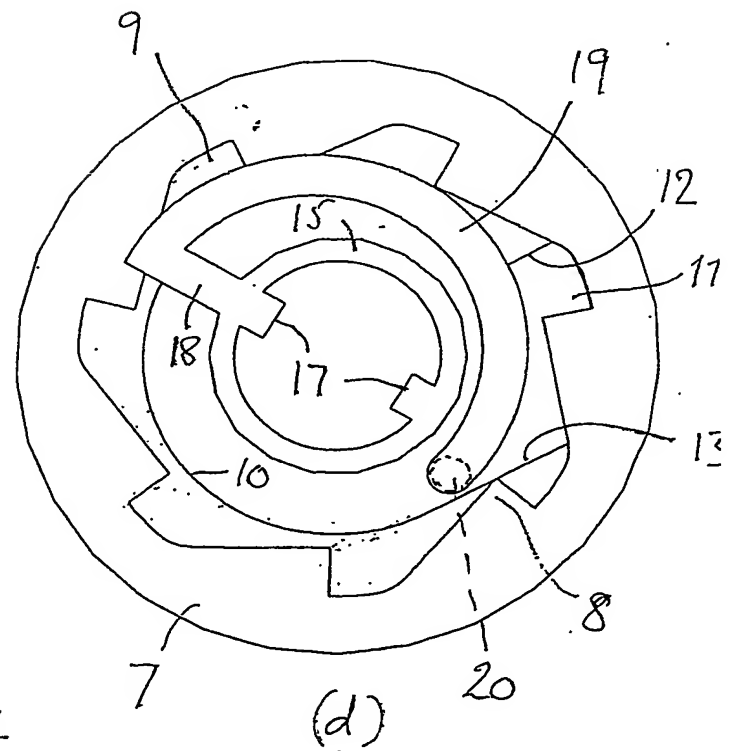
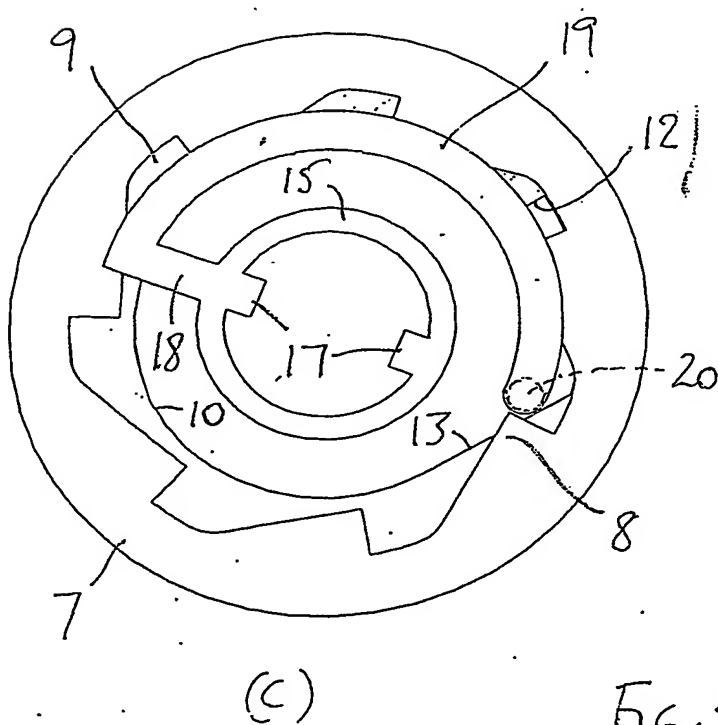
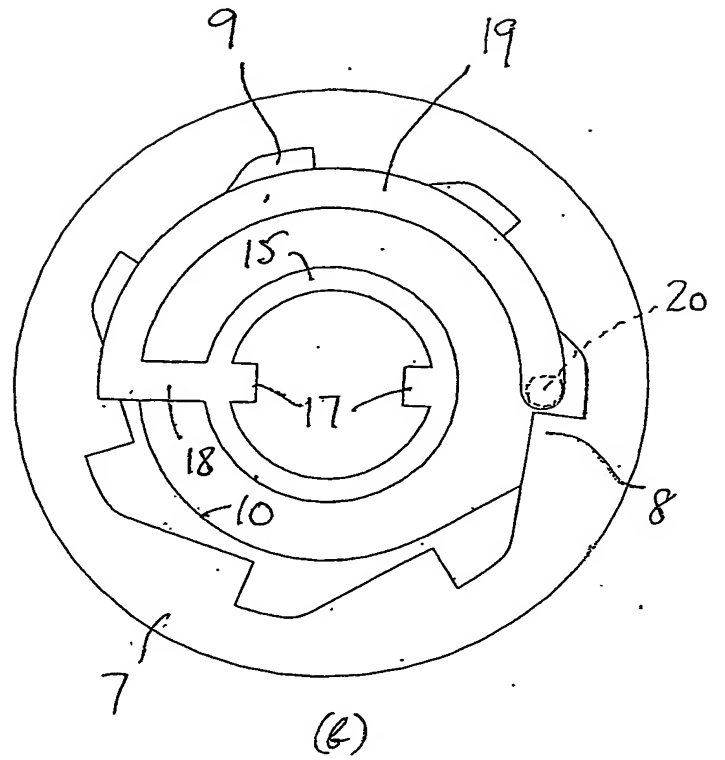
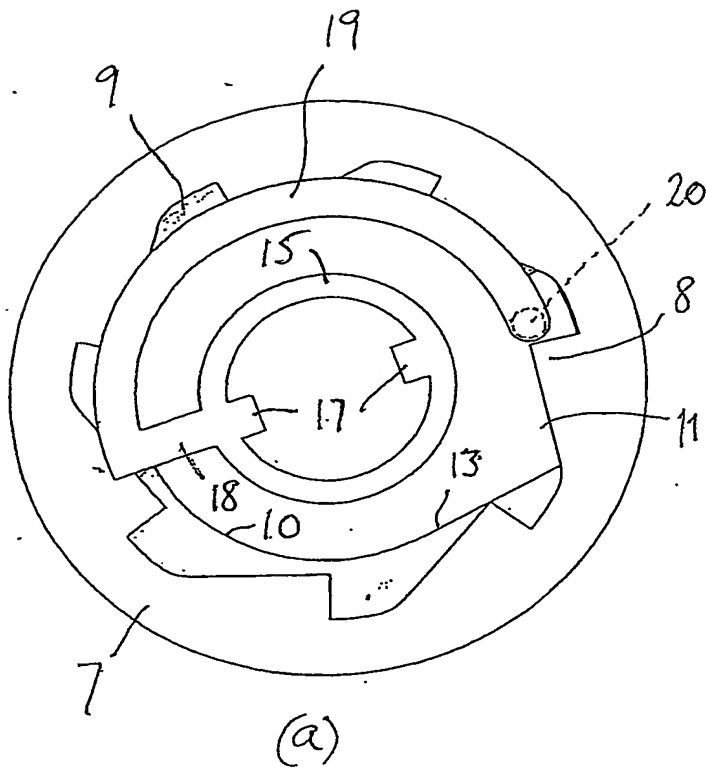


FIG. 4

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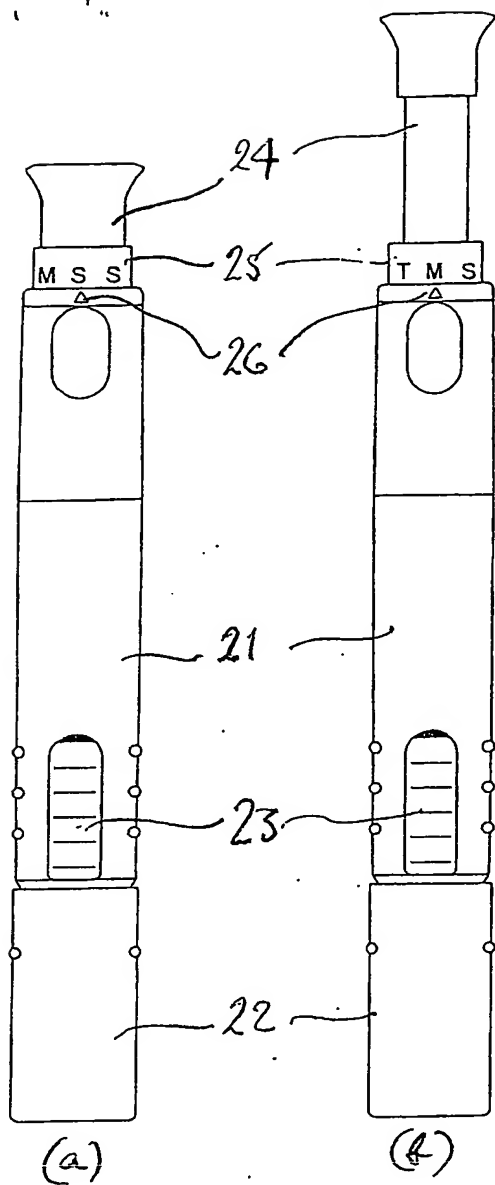


Fig. 5

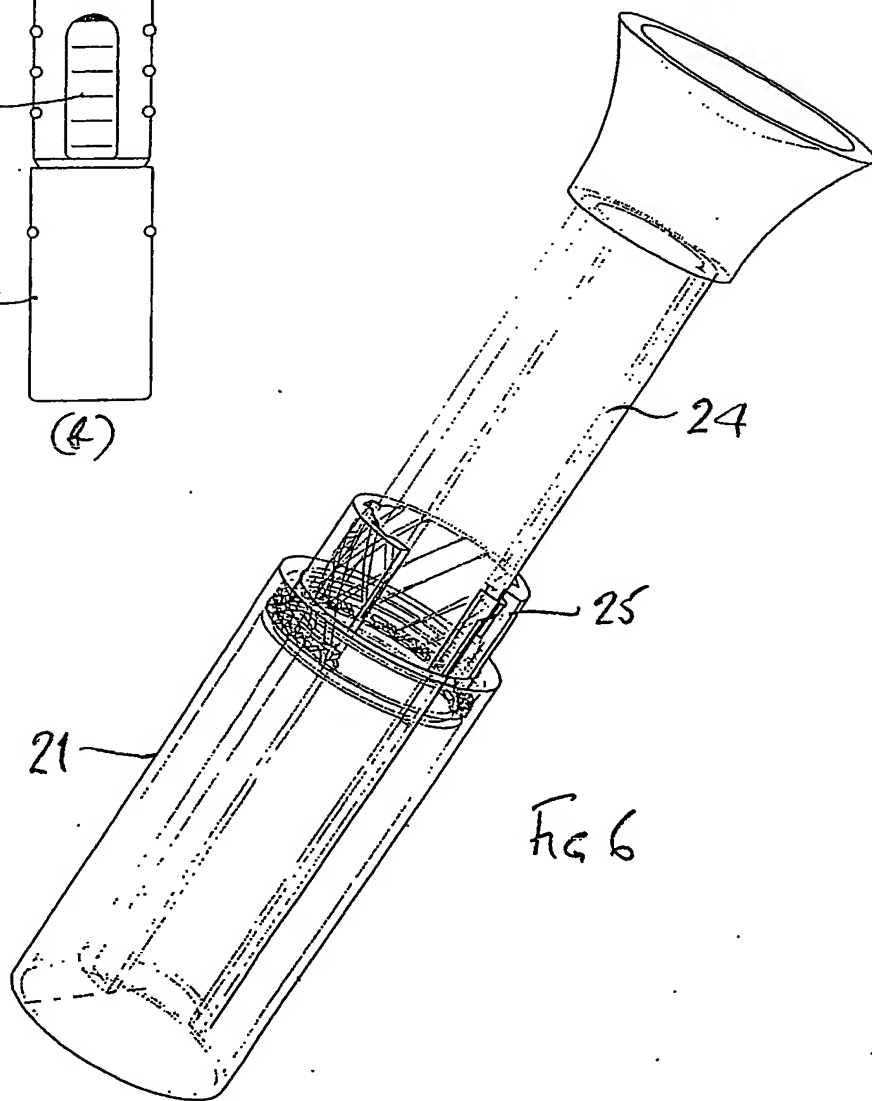


Fig. 6

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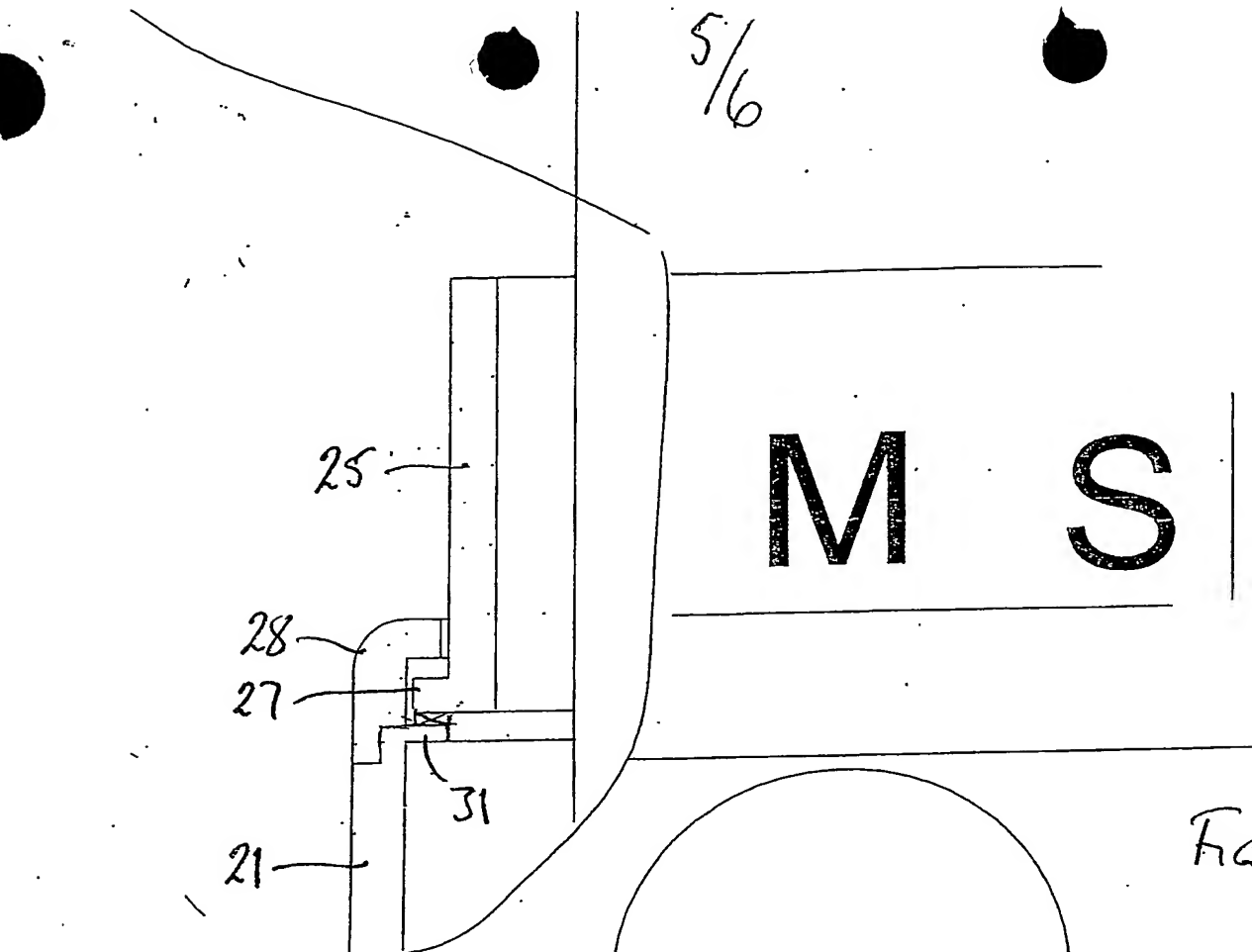


Fig 7

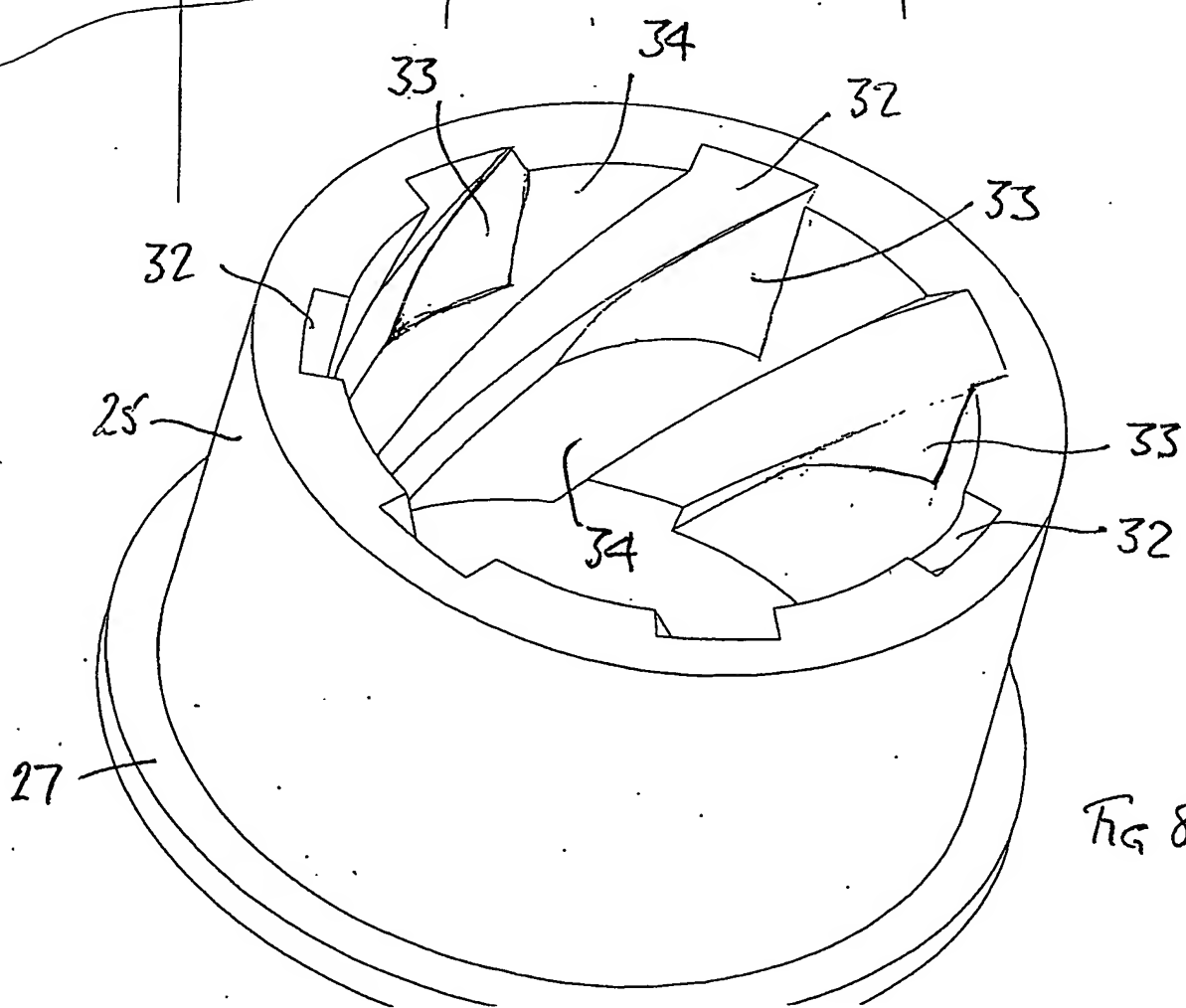
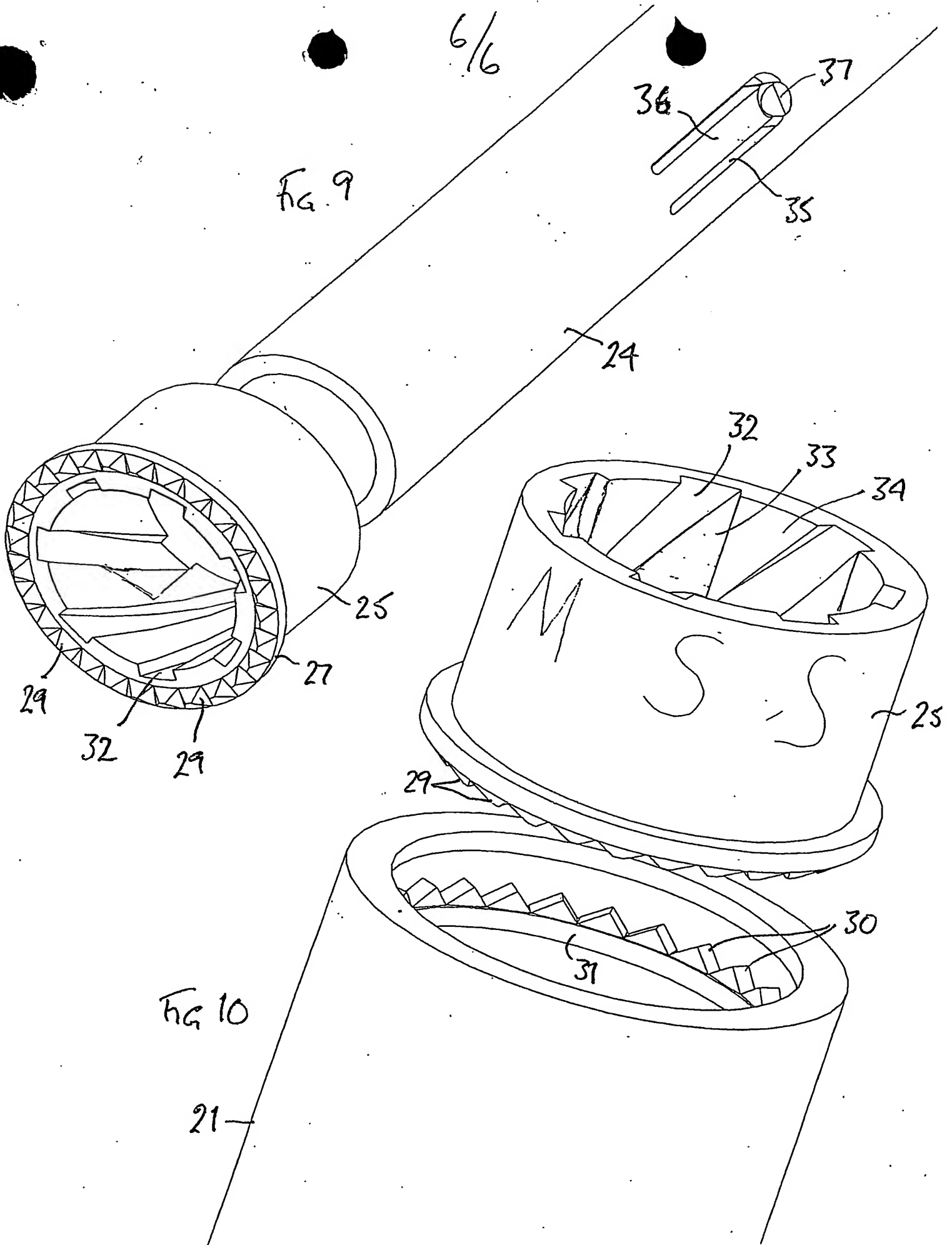


Fig 8

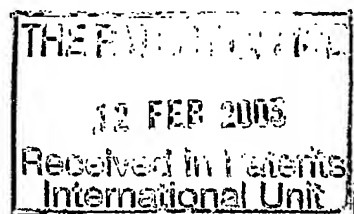
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Fig. 9



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